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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,892	REED ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-96* is/are pending in the application.

4a) Of the above claim(s) *69-76 and 83-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67,68,77-82 and 87-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 67-96 are pending in the present application. Claims 69-76 and 83-86 stand withdrawn further consideration as being drawn to a nonelected invention. Claims 67, 68, 77-83 and 87-96 stand rejected as indicated below.

Claim Rejections - 35 USC § 112

3. The rejection of claims 68, 78, 80, 82, 88, 90, 91, 93 and 94 under 35 USC 112, fist paragraph is maintained.

Applicant argues the skilled artisan in the art would understand which cancer are endocrine-dependent and that any tumors or cancers which develops in hormone-regulated organs would be inclusive. Applicant also argues a steroid sulphatase is an enzyme that promotes growth of tumors in hormone-regulated organs and, thus, steroid sulphatase inhibitor can be used for treating the endocrine-dependent cancer. Applicant's argument was considered but not persuasive for the following reasons.

Based on the function of the endocrine system, applicant is arguing the utilization of the claimed compounds in treating most, if not all, tumors/cancers. However, the art lacks teaching of a single agent in treating most/all cancers. Additionally, the fact that a

tumor/cancer develops in a hormone-regulated organ does not follow that said tumor/cancer is due to stimulation by a hormone, i.e., endocrine-dependent. Applicant has not provided any evidence that would support his argument that any tumor/cancer that develops in a hormone-regulated organ, which would be inclusive of most, if not all tumors/cancers, would be endocrine dependent or hormone regulated.

The endocrine system is a system of glands that have a wide array of functions (see the attached Wikipedia article). From the table provided, there is a vast array of hormones, steroidal and nonsteroidal, secreted by a variety of glands such as the hypothalamus, pituitary, thyroid, parathyroid, heart, muscle, skin etc. As noted above, the medical art lacks any teaching of a single agent that would treat tumors/cancers irrespective of the site of said and the present specification lacks guidance of the utilization of the claimed compounds in treating other cancers apart from breast cancer.

For this reason and those given in the previous Office Action, the rejection of claims 68, 78, 80, 82, 88, 90, 91, 93 and 94 under 35 USC 112, fist paragraph is maintained.

4. The rejection of claims 68, 78, 80, 82, 88 and 90-96 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant argues that one of skilled in the art would know that the endocrine system is a hormone producing system and therefore tumors/cancers which develop in

hormone-regulated organs are endocrine-dependent. Applicant's argument was considered but not persuasive for the following reasons.

As noted above in #3, the endocrine system secretes numerous hormones, steroidal and nonsteroidal, from a variety of glands. Said hormones are involve in most, if not, every organ system in the human body (see Table of attached Wikipedia article) and, thus, applicant's argument would imply that most, if not, every tumor/cancer would be treatable utilizing the claimed compounds. However, the art lacks teaching of every tumor/cancer being "hormone-regulated" and, thus, endocrine-dependent and applicant has not provided any evidence on record to support his argument.

For this reason and those given in the previous Office Action, the rejection of claims 68, 78, 80, 82, 88 and 90-96 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is maintained.

5. The rejection of claims 67, 77, 79, 81, 87, 89 and 93-95 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

6. The rejection of claim 96 under 35 USC 112, second paragraph is withdrawn.

7. The rejection of claims 68, 78, 80, 82, 88 and 93 under 35 USC 112, second paragraph is maintained.

Applicant's argues the skilled artisan in the art would be able to determine the metes and bound of the recitation of "endocrine-dependent cancer". According to applicant, any tumor/cancer which develops in hormone-regulated endocrine tissues would be included. Applicant's argument was considered but not persuasive for the following reason.

As noted above in #s 3 and 4, the hormones produced by the endocrine system affect most, if not all, tissue in the human body. However, the art does not attribute every tumor/cancer to the endocrine-system and, thus, the skilled artisan would not expect that every tumor/cancer would be endocrine dependent. Therefore, said skilled artisan would be unable to determine the metes and bound of the claimed invention.

For this reason and those given in the previous Office Action, the rejection of claims 68, 78, 80, 82, 88 and 93 under 35 USC 112, second paragraph is maintained.

Double Patenting

8. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 5,616,574 is maintained.

Applicant argues the finding of obviousness-type double patenting over claims in the present application turns on whether the invention defined in the instant claim(s) is an obvious variation of the invention defined in the prior patent claim(s) and the disclosure in the prior patent may not be used as prior art. Applicant also argues (a) the instant claims are drawn to the methods of inhibiting steroid sulphatase activity and

treating endocrine-dependent cancer by the administration of a non-oestrogenic estrone-3-sulphamate having a substituent at one or more of the 2- and 4-positions; (b) the claimed compounds are vastly superior to previous steroid sulphatase inhibitors and (c) the substituted oestrone of the cited reference would not inherently lack estrogenic activity because said activity is not taught, disclosed or suggested by the reference. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claimed invention is a method of inhibiting steroid sulphatase activity or treating endocrine-dependent cancer by administering a non-oestrogenic estrone-3-sulphamate having a substituent at one or more of the 2- and 4-positions. The claims of the cited reference are drawn to compounds and compositions comprising a number of steroid sulphamates such as estrone-3-sulphamate and substituted derivatives thereof.

The examiner agrees that ODP is based on the claims of the cited reference and the instant claims and that the disclosure can not be used as prior art. However, in order to define the invention of the claims of the cited reference, the portion(s) of the specification which provide support for the patent claims can be examined and considered (see MPEP § 804, B(1)). In other words, the specification is utilized to define obvious variation of the claimed invention of the cited reference. In that light, the specification of '574 discloses (a) the utilization of the claimed compounds and compositions in inhibiting steroid sulphatase activity and treating estrogen-dependent tumors such as breast cancer and (b) substituted estrones such as 2-methoxy-estrone. Therefore, utilizing 2-methoxy-oestrone in inhibiting steroid sulphatase activity as well

as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant argues the reference does not teach, disclose or suggest the substituted estrone would inherently lack estrogenic activity. However, the fact that the reference does not teach, disclose or suggest the nonestrogenic activity as presently claimed does not eliminate the instantly claimed compound(s) from the scope of the prior art claims or make said compound(s) less obvious.

The issue is whether said compound(s) is an obvious variant of the prior art claim(s). Here, the prior art claims recite "substituted estrones" and the specification discloses "2-methoxy-estrone" as an example of a substituted estrone. The fact that applicant has discovered that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compound/composition.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 5,616,574 is maintained.

9. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 5,830,886 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity comprising administering a ring system compound which comprises a polycyclic ring to which is attached a sulphamate group and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of compounds inclusive of steroid sulphamates such as "substituted oestrone".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies seven "substituted oestrone" including "2-methoxy-oestrone" and discloses the claimed

compounds are useful in treating estrogen dependent tumors. Therefore, utilizing 2-methoxy-oestrone in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "substituted oestrones" is recited by the claims of the cited patent and the use of 2-methoxy-oestrone as recited by the prior art claims is rendered obvious by the disclosure of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 5,830,886 is maintained.

10. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,011,024 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity comprising administering a ring system compound which comprises a ring system to which is attached a sulphamate group and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of compounds inclusive of steroid sulphamates such as "2-methoxy-EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2- and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in

breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,011,024 is maintained.

11. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,159,960 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity comprising administering a compound which comprises a ring system to which is attached a sulphamate group and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method of inhibiting steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of compounds inclusive of steroid sulphamates such as "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2- and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in

breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,159,960 is maintained.

12. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,187,766 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a compound having a ring system to which is attached a sulphamate group and wherein said compound is an inhibitor of an enzyme having steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a compound having a ring system to which is attached a sulphamate group and wherein said compound is an inhibitor of an enzyme having steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of compounds which is inclusive of "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2-

and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,187,766 is maintained.

13. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,476,011 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method for introducing an estrogenic compound into a subject in need thereof wherein the compound is an inhibitor of an enzyme having steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic17 inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method for introducing an estrogenic compound into a subject in need thereof wherein the compound is an inhibitor of an enzyme having steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of steroid sulphamates which is inclusive of "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2-

and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,476,011 is maintained.

14. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,642,397 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a purified compound having a polycycle ring system wherein the compound is an inhibitor of an enzyme having steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a purified compound having a polycycle ring system wherein the compound is an inhibitor of an enzyme having steroid sulphatase activity. The claims of the cited reference teaches the use of a genus of steroid sulphamates which is inclusive of "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2- and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid

sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,642,397 is maintained.

15. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,676,934 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a composition comprising a polycyclic sulphamate compound wherein the compound inhibits steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, (a) one can not look to the specification or other prior art sources to address any differences between the claims and (b) the skilled artisan in the art would not be able to predict the cited composition of the prior art having tumor necrosis factor α in addition to the sulphamate compound could be administered to a patient in need of inhibition of steroid sulphatase activity by a compound with reduced oestrogenicity. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a composition comprising a polycyclic sulphamate compound wherein the compound inhibits steroid sulphatase activity. The claims of the cited reference recites the use of "2-methoxyoestrone-3-O-sulphamate".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the

issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference discloses the use of the prior art composition to inhibit the growth of breast cancer cells by induction of apoptosis (see col. 21, lines21-65) and, thus, renders obvious the use of 2-methoxy EMATE in treating tumors such as breast cancer. The claims of the cited reference recites the ability of the compounds to inhibit steroid sulphatase activity and, thus, the ability of the prior art composition to inhibit steroid sulphatase activity would also be obvious. Applicant has not provided any evidence on record to contradict the ability of the claimed composition to inhibit steroid sulphatase activity.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,676,934 is maintained.

16. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,677,325 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method for inhibiting estrone or estradiol production comprising administering a ring system compound having a sulfamic ester wherein the compound is an inhibitor of an enzyme having steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method for inhibiting estrone or estradiol production comprising administering a ring system

compound having a sulfamic ester. The claims of the cited reference teaches the use of a genus of steroid sulphamates which is inclusive of "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2- and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,677,325 is maintained.

17. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,903,084 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a composition comprising a polycyclic sulphamate compound wherein the compound inhibits steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, (a) one can not look to the specification or other prior art sources to address any differences between the claims and (b) the skilled artisan in the art would not be able to predict the cited composition of the prior art having tumor necrosis factor α in addition to the sulphamate compound could be administered to a patient in need of inhibition of steroid sulphatase activity by a compound with reduced

oestrogenicity. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a composition comprising a polycyclic sulphamate compound wherein the compound inhibits steroid sulphatase activity. The claims of the cited reference recites the use of "2-methoxyoestrone-3-O-sulphamate".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference discloses the use of the prior art composition to inhibit the growth of breast cancer cells by induction of apoptosis (see col. 21, lines21-65) and, thus, renders obvious the use of 2-methoxy EMATE in treating tumors such as breast cancer. The claims of the cited reference recites the ability of the compounds to inhibit steroid sulphatase activity and, thus, the ability of the prior art composition to inhibit steroid sulphatase activity would also be obvious. Applicant has not provided any evidence on record to contradict the ability of the claimed composition to inhibit steroid sulphatase activity.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of

"2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 6,903,084 is maintained.

18. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,067,503 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a compound and a composition comprising a compound of formula IV as defined by the prior art and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a

treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a compound of formula IV as defined by the prior art. The claims of the cited reference teaches the use of a genus of steroid sulphamates which is inclusive of "2-methoxy EMATE".

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several A-ring substituted EMATEs including "2-methoxy-EMATE". The prior art also discloses the prior art compounds inhibit steroid sulphatase activity and are useful in treating tumors such as breast cancer cells. Therefore, the use 2-methoxy-EMATE in inhibiting steroid sulphatase activity and in the treatment of breast cancer are rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat breast

cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious in view of the claimed invention of the cited reference. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,067,503 is maintained.

19. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,078,395 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a method of treating a hormone independent cancer wherein said cancer is susceptible to being treated by inhibition or arresting of cell cycling comprising administering a polycyclic compound to which is attached a Group I and a Group II and there is no reasonable expectation said compounds would be useful as

nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a method of treating a hormone independent cancer. The claims of the cited reference teach the use of a genus of compounds inclusive of steroid sulphamates such as "2-methoxy-EMATE" and the treatment of breast cancer (see especially claims 18 and 30). In essence, the condition treated by the prior art compound, for example, 2-methoxy-EMATE, is encompassed by the claimed invention and, thus, the claimed invention is rendered anticipated.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and that "breast cancer" is hormone independent cancer. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy-EMATE" in treating breast cancer is encompassed by the claims of the cited patent and, thus, is rendered anticipated by the prior art claims. The fact that applicant discovers that the claimed prior art compounds have lower estrogenic activity do not make said compounds unobvious.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,078,375 is maintained.

20. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,098,199 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a compound having a steroidal ring structure to which is attached a sulphamate group and wherein said compound is an inhibitor of an enzyme having steroid sulphatase activity and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a compound having a steroidal ring structure to

which is attached a sulphamate group and wherein said compound is an inhibitor of an enzyme having steroid sulphatase activity. The claims of the cited reference teach a genus of compounds which are inhibitors of an enzyme having steroid sulphatase activity.

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference exemplifies several 2- and/or 4-substituted EMATEs including "2-methoxy-EMATE" as well as their effect in breast cancer cells. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor is rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat estrogen dependent cancer such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid

sulphatase inhibitors does not make said compounds unobvious. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,098,199 is maintained.

21. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,119,081 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a compound of formula (IVa) having sulphamate groups attached thereto and wherein the 3-position is substituted with a hydrocarbyl or oxyhydrocarbyl group and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a compound of formula (IVa) having sulphamate groups attached thereto and wherein the 3-position is substituted with a hydrocarbyl or oxyhydrocarbyl group, for example, 2-methoxy-E2bisMATE (see claim 11 of the cited patent).

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference discloses the use of the prior art compounds in treating breast cancer (see col. 9, lines 5-6 of the cited reference). Therefore, utilizing 2-methoxy-E2bisMATE in the treatment of breast cancer is rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy E2bisMATE" in the treatment of breast cancer is rendered obvious by the claims of the cited patent. The fact that applicant discovers that some of the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious. The skilled artisan in the art would expect differences in the efficacy of the prior art compounds.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,119,081 is maintained.

22. The rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,211,246 is maintained.

Applicant argues the reference does not teach using a non-oestrogenic 2- and 4-substituted estrone-3-sulphamate. According to applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a sulphamate compound wherein an (oxy)hydrocarbyl group is attached to the 2-position and an apoptosis inducer and there is no reasonable expectation said compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase and as a treatment of endocrine-dependent cancer as taught by the pending claims. Applicant also argues, one can not look to the specification or other prior art sources to address any differences between the claims. Applicant's argument was considered but not persuasive for the following reasons.

As noted by applicant, the claims of the cited reference are drawn to a pharmaceutical composition comprising a sulphamate compound wherein an

(oxy)hydrocarbyl group is attached to the 2-position, for example, 2-methoxy-EMATE (see claim 6 of the cited patent). The claims of the cited patent also teach the use of the prior art compounds as inhibitors of estrone sulphatase (see claim 10 of the cited patent).

The MPEP allows the utilization of portions of the specification which provide support for the claimed invention to be examined and considered when addressing the issue of whether a claim defines an obvious variation of the claimed invention (see MPEP sec 804, B(1)). The specification of the cited reference teaches the use of the prior art compounds in treating tumors such as breast cancer. Therefore, utilizing 2-methoxy-EMATE in inhibiting steroid sulphatase activity as well as in the treatment of estrogen dependent tumor is rendered obvious by the claims of the cited reference.

Applicant also argues the claims do not make obvious that the claimed prior art compounds would be useful as nonoestrogenic inhibitors of steroid sulphatase. The issue is not whether the cited reference teaches that which was disclosed by applicant but whether the utilization of the claimed compounds as recited by the instant claims is obvious based on the claims of the cited reference. As noted above, the utilization of "2-methoxy EMATE" to inhibit steroid sulphatase activity as well as to treat tumors such as breast cancer are rendered obvious by the claims of the cited patent. The fact that applicant discovers that the claimed prior art compounds have lower estrogenic activity and/or might be more potent steroid sulphatase inhibitors does not make said compounds unobvious.

In summary, the claimed invention is rendered obvious in view of the claims of the cited reference utilizing the specification of the cited reference as a dictionary to define the obvious variants of the claims.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of US Patent No. 7,211,246 is maintained.

23. The provisional rejections of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of copending Applications No. 11/233,945; 11/234,868; 11/244,416; 11/368,367 and 11/406,079 are maintained.

Applicant statement that the Office Action "indicated that although the rejections are provisionally, the rejections can not be held in abeyance" is noted but incorrect. The examiner was unable to find said comment.

Applicant's statement that the provisional obviousness-type double patenting rejections will be addressed at the time allowable subject matter is determined in the present application is noted.

For this reason and those given in the previous Office Action, the provisional rejection of claims 67, 68, 77-82 and 87-96 on the ground of nonstatutory obviousness-type double patenting over claims of copending Applications No. 11/233,945; 11/234,868; 11/244,416; 11/368,367 and 11/406,079 are maintained.

Claim Rejections - 35 USC § 103

24. The rejection of claims 67, 68, 77-82 and 87-96 under 35 USC 103(a) over Reed et al. (WO 93/05064).

Applicant argues the reference does not teach or suggest (a) inhibiting steroid sulphatase activity utilizing a non-oestrogenic sulphamate compound and (b) that 2-methoxy-estrone sulphamate exemplified by the reference would have surprisingly superior properties over any of the other compounds. Applicant also argues Purohit shows substitution at the 2- or 4-position of EMATE result in compounds with vastly superior activity as compared to the previous steroid sulphatase inhibitors. Accordingly, it is applicant's position that the present invention is patentable over the cited reference.

There is no requirement that the reference must teach the compounds are non-oestrogenic as discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, USPQ 2d 1897, 1904 (Fed. Cir. 1990). An obviousness rejection is proper as long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation differs from that discovered by applicant.

As noted in the previous Office Action, Reed teaches steroid sulphamates and their use in treating estrogen dependent cancers such as breast cancer. The reference exemplifies a number of steroidal ring systems including 2-methoxy-estrone. Thus, the skilled artisan would have the reasonable expectation that the corresponding 2-methoxy EMATE as encompassed by the genus taught by Reed would be useful as taught by the

reference. Applicant has not provided any evidence that the claimed compound would not have been obvious based on the prior art.

Applicant also argues the superior properties of the claimed compounds. Again, as noted in the previous Office Action, the finding that one prior art compound is more efficacious over other prior compounds is not surprising because the skilled artisan in the art would expect differences in the potency of the prior art compounds.

For these reasons and those given in the previous Office Action, the rejection of claims 67, 68, 77-82 and 87-96 under 35 USC 103(a) over Reed et al. (WO 93/05064).

Request for Interview

25. The examiner notes applicant has been granted a number of interviews in the present application. Because the issue(s) in the application is the same, applicant's request for another interview is denied. The examiner is open to discussion if the issues to be discussed differ from those previously discussed. In that light, applicant is invited to call the examiner to set a date and time as well as to provide the examiner with the issue(s) to be discussed.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612